STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Office Of Laboratory Quality Assurance

Chapter 246-338 WAC
MEDICAL TEST SITE RULES
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WAC

CHAPTER 246-338

MEDICAL TEST SITE RULES

WAC 246-338-001 PURPOSE
The purpose of this chapter is to implement chapter 70.42 RCW, by establishing licensing standards for medical test sites, consistent with federal law and regulation, related to quality control, quality assurance, records, personnel requirements, proficiency testing, and licensure waivers.

WAC 246-338-010 DEFINITIONS
For the purposes of this chapter, the following words and phrases have these meanings unless the context clearly indicates otherwise.

(1) "Accreditation organization" means a public or private organization or agency approved by CMS as having standards which are consistent with federal law and regulation, and judged by the department to be equivalent to this chapter.

(2) "Authorized person" means any individual allowed by Washington state law or rule to order tests or receive test results.

(3) "Biannual verification" means a system for verifying the accuracy of test results, at least twice a calendar year, for those tests for which proficiency testing is not required by the department.

(4) "Calibration" means a process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

(5) "Calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results.

(6) "Calibrator" means a material, solution, or lyophilized preparation designed to be used in calibration. The values or concentrations of the analytes of interest in the calibration material are known within limits ascertained during its preparation or before use.

(7) "Case" means any slide or group of slides, from one patient specimen source, submitted to a medical test site, at one time, for the purpose of cytological or histological examination.

(8) "CDC" means the federal Centers for Disease Control and Prevention.

(9) "CMS" means the federal Centers for Medicare & Medicaid Services.

(10) "CLIA" means Section 353 of the Public Health Service Act, Clinical Laboratory Improvement Amendments of 1988, and regulations implementing the federal amendments, 42 CFR Part 493–Laboratory Requirements in effect on September 22, 2003.

(11) "Control" means a material, solution, lyophilized preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the analytes of interest in the control material are known within limits ascertained during its preparation or before routine use.

(12) "Control slide" means a preparation of a material known to produce a specific reaction which is fixed on a glass slide and is used in the process of quality control.

(13) "Days" means calendar days.

(14) "Deemed status" means recognition that the requirements of an accreditation organization have been judged to be equal to, or more stringent than, the requirements of this chapter and the CLIA requirements, and the accreditation organization has agreed to comply with all requirements of this chapter and CLIA.

(15) "Deficiency" means a finding from an inspection or complaint investigation that is not in compliance with this chapter and requires corrective action.

(16) "Department" means the department of health.

(17) "Direct staff time" means all state employees' work time; travel time; telephone contacts and staff or management conferences; and expenses involved with a complaint investigation or an on-site follow-up visit.

(18) "Director", defined as the designated test site supervisor in RCW 70.42.010, means the individual responsible for the technical functions of the medical test site. This person must meet the qualifications for Laboratory Director, listed in 42 CFR Part 493 Subpart M-Personnel for Nonwaived Testing.

(19) "Disciplinary action" means license or certificate of waiver denial, suspension, condition, revocation, civil fine, or any combination of the preceding actions, taken by the department against a medical test site.

(20) "Facility" means one or more locations within one campus or complex where tests are performed under one owner.

(21) "Forensic" means investigative testing in which the results are never used for clinical diagnosis, or referral to a health care provider for treatment of an individual.

(22) "HHS" means the federal Department of Health and Human Services.

(23) "High complexity" means a test system, assay, or examination that is categorized under CLIA as a high complexity test.

(24) "May" means permissive or discretionary.

(25) "Medical test site" or "test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A medical test site does not mean:

(a) A facility or site, including a residence, where a test approved for home use by the Federal Food and Drug Administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction; or

(b) A facility or site performing tests solely for forensic purposes.

(26) "Moderate complexity" means a test system, assay, or examination that is categorized under CLIA as a moderate complexity test.

(27) "Must" means compliance is mandatory.

(28) "Nonwaived" means all tests categorized under CLIA as:

(a) Moderate complexity tests, including provider-performed microscopic procedures; or

(b) High complexity tests.

(29) "Owner" means the person, corporation, or entity legally responsible for the business requiring licensure or a certificate of waiver as a medical test site under chapter 70.42 RCW.

(30) "Performance specification" means a value or range of values for a test that describe its accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range.

(31) "Person" means any individual, public organization, private organization, agent, agency, corporation, firm, association, partnership, or business.

(32) "Physician" means an individual with a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine, or equivalent degree who is a licensed professional under chapter 18.71 RCW Physicians; chapter 18.57 RCW Osteopathy - Osteopathic medicine and surgery; or chapter 18.22 RCW Podiatric medicine and surgery.

(33) "Provider-performed microscopic procedures" means only those moderate complexity tests listed under WAC 246-338-020(2)(b)(i) through (x), when the tests are performed in conjunction with a patient's visit by a licensed professional meeting qualifications specified in WAC 246-338-020 (2)(a)(i) through (vi).

(34) "Provisional license" means an interim approval issued by the department to the owner of a medical test site.

(35) "Records" means books, files, reports or other documentation necessary to show compliance with the quality control and quality assurance requirements under this chapter.

(36) "Reference material" means a material or substance, calibrator, control or standard where one or more properties are sufficiently well established for use in calibrating a process or for use in quality control.

(37) "Specialty" means a group of similar subspecialties or tests. The specialties for a medical test site are as follows:
(a) Chemistry;
(b) Cytogenetics;
(c) Diagnostic immunology;
(d) Immunohematology;
(e) Hematology;
(f) Histocompatibility;
(g) Microbiology;
(h) Pathology; and
(i) Radiobioassay.

(38) "Standard" means a reference material of fixed and known chemical composition capable of being prepared in essentially pure form, or any certified reference material generally accepted or officially recognized as the unique standard for the assay regardless of level or purity of the analyte content.

(39) "Subspecialty" means a group of similar tests. The subspecialties of a specialty for a medical test site are as follows, for:
(a) Chemistry, the subspecialties are routine chemistry, urinalysis, endocrinology, and toxicology;
(b) Diagnostic immunology, the subspecialties are syphilis serology and general immunology;
(c) Immunohematology, the subspecialties are ABO Grouping and Rh typing, antibody detection, antibody identification, and compatibility testing;
(d) Hematology, the subspecialties are routine hematology and coagulation;
(e) Microbiology, the subspecialties are bacteriology, mycology, parasitology, virology, and mycobacteriology; and
(f) Pathology, the subspecialties are histopathology (including dermatopathology), diagnostic cytology, and oral pathology.

(40) "Supervision" means authoritative procedural guidance by an individual qualified under 42 CFR Part 493 Subpart M – Personnel for Nonwaived Testing, assuming the responsibility for the accomplishment of a function or activity by technical personnel.

(41) "Technical personnel" means individuals employed to perform any test or part of a test.

(42) "Test" means any examination or procedure conducted on a sample taken from the human body.

(43) "Validation inspection" means an on-site inspection by the department of an accredited medical test site to determine that the accreditation organization's regulations are equivalent to this chapter and are enforced.

(44) "Waived test" means a test system that is:
(a) Cleared by the Food and Drug Administration for home use; or
(b) A simple laboratory examination or procedure that has an insignificant risk of an erroneous result.

In order for a test system to be waived, it must be approved for waiver under CLIA.

(45) "Will" means compliance is mandatory.

WAC 246-338-020 LICENSURE—TYPES OF MEDICAL TEST SITE LICENSES

After July 1, 1990, any person advertising, operating, managing, owning, conducting, opening, or maintaining a medical test site must first obtain a license from the department. License types are described in Table 020-1.

(1) **Certificate of Waiver**
Applicable if the medical test site performs only the tests classified as waived.

(2) **Provider Performed Microscopic Procedures (PPMP)**
Applicable if the medical test site restricts its testing performance to one or more of the following moderate complexity tests performed by one of the licensed professionals listed, in conjunction with a patient's visit. In addition, the medical test site can perform tests classified as waived with this type of license.

(a) PPMP may be performed only by one of the following licensed professionals:
(i) Physician licensed under chapter 18.71 RCW, Physicians; chapter 18.57 RCW, Osteopathy--Osteopathic medicine and

surgery; or chapter 18.22 RCW, Podiatric medicine and surgery;

(ii) Advanced registered nurse practitioner, licensed under chapter 18.79 RCW, Nursing care;

(iii) Midwife licensed under chapter 18.50 RCW, Midwifery;

(iv) Physician assistant licensed under chapter 18.71A RCW, Physician assistants;

(v) Naturopath licensed under chapter 18.36A RCW, Naturopathy; or

(vi) Dentist licensed under chapter 18.32 RCW, Dentistry.

(b) Microscopic procedures authorized under a PPMP license are:

(i) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements;

(ii) All potassium hydroxide (KOH) preparations;

(iii) Pinworm examinations;

(iv) Fern tests;

(v) Post-coital direct, qualitative examinations of vaginal or cervical mucous;

(vi) Urine sediment examinations;

(vii) Nasal smears for granulocytes;

(viii) Fecal leukocyte examinations;

(ix) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility); and

(x) Any other tests subsequently categorized under CLIA as provider-performed microscopy procedures.

(3) **Moderate/High Complexity**

(a) **Low Volume, Category A-J**, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived or qualified as PPMP under subsection (2) of this section. Under this type of license, the medical test site may also perform tests classified as waived.

(b) **Accredited: Low Volume, Category A-J**, as described in Table 990-1.

Applicable if the medical test site performs any tests that are not classified as waived, and is accredited **and** inspected by an accreditation organization approved by the department under WAC 246-338-040. Under this type of license, the medical test site may also perform tests classified as waived.

020-1 Table of Requirements for Each License Type

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
(1) Certificate of Waiver	• Restrict testing to tests classified as waived. • Meet the requirements of WAC 246-338-020 Licensure -Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections. • Follow manufacturers' instructions for performing the test.	• Complaint • Technical assistance	• When indicated
(2) PPMP	• Restrict testing to tests classified as PPMP or waived. • Meet the requirements of WAC 246-338-020 Licensure -Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing the test.	• Complaint • Technical assistance	• When indicated
(3) Moderate/High Complexity **(a) Low Volume, Category A-J**	• Perform tests classified as moderate or high complexity. • Meet the requirements of WAC 246-338-020 Licensure -Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control. • Follow manufacturers' instructions for performing test.	• Initial • Routine • Complaint • On-site follow-up • Technical assistance	• First 6 months of license • Every 2 years • When indicated • When indicated • When indicated

(b) Accredited: Low Volume, Category A-J	• Perform tests classified as moderate or high complexity.
	• Meet the requirements of WAC 246-338-020 Licensure -Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections; WAC 246-338-050 Proficiency Testing (if applicable); WAC 246-338-060 Personnel; WAC 246-338-070 Records; WAC 246-338-080 Quality Assurance; WAC 246-338-090 Quality Control.
	• Follow manufacturers' instructions for performing the test.
	• Submit to the department upon request, or authorize the accreditation organization to submit:
	  • Proof of accreditation;
	  • On-site inspection results;
	  • Statement of deficiencies;
	  • Plan of correction for the deficiencies cited;
	  • Any disciplinary action and results of any disciplinary action taken by the accreditation organization against the medical test site.
		• Validation
		• Complaint
		• On-site follow-up
		• Technical assistance
			• 2.5% of accredited sites annually
			• When indicated
			• When indicated
			• When indicated

WAC 246-338-022 INITIAL APPLICATION FOR MEDICAL TEST SITE LICENSE

(1) Application Procedure

Applicants requesting a medical test site license must:

(a) Submit a completed application on forms furnished by the department, signed by the owner or authorized representative;

(b) File a separate application for each test site **except** under the following conditions:

(i) If the test site is not at a fixed location and moves from testing site to testing site, or uses a temporary testing location such as a health fair, the medical test site may apply for a single license for the home base location;

(ii) If the medical test site is a not-for-profit or state or local government and performs a combination of fifteen or less of either waived or moderate complexity test procedures at different locations, the owner may file an application for a single license;

(c) Furnish full and complete information to the department in writing:

(i) Name, address, phone number, and federal tax ID number of the medical test site;

(ii) Name of owner;

(iii) Number and types of tests performed, planned, or projected;

(iv) Name and qualifications including educational background, training, and experience of the director;

(v) Names and qualifications including educational background, training, and experience of technical personnel, if requested by the department;

(vi) Name of proficiency testing program or programs used by the medical test site and a copy of the enrollment confirmation form, if applicable;

(vii) Methodologies for tests performed, if requested by the department; and

(viii) Other information as requested by the department;

(d) Submit the designated fee in the time period indicated, upon receipt of a fee statement from the department;

(e) If applying for an accredited license, submit proof of accreditation by an approved accreditation organization. If application has been made to an accreditation organization, submit a copy of the application, followed by proof of accreditation within eleven months of issuance of the medical test site license.

(2) Issuing an Initial License

(a) An initial license will be issued for a medical test site when the applicant:

(i) Submits a completed application and any information requested by the department;

(ii) Pays the designated license fee; and

(iii) Meets the requirements of chapter 70.42 RCW and this chapter.

(b) License expiration dates will be based on a two-year licensure cycle, expiring on October 31st of even-numbered years. The license period for an initial license begins the day of the month that payment is received and expires on October 31st of the current or next even-numbered year.

(c) The department may issue a provisional license valid for a period of up to two years when a medical test site applies for licensure for the first time.

(d) The department will terminate a provisional license at the time a two-year license for the medical test site is issued.

(e) License fees are listed under WAC 246-338-990.

WAC 246-338-024 LICENSE RENEWAL / REAPPLICATION PROCESS

(1) The department will issue a renewal license for a medical test site when the owner:

(a) At least thirty days prior to the expiration date of the current license, submits a completed renewal application form, available from the department, in compliance with WAC 246-338-022(1) and submits the designated fee; and

(b) Meets the requirements of chapter 70.42 RCW and this chapter.

(2) A license is issued for a period of two years. License expiration dates are based on a two-year cycle, expiring on October 31st of even-numbered years.

(3) The department may extend a license for a period not to exceed six months beyond the expiration date of the license.

(4) The department will require the owner of the medical test site to reapply for a license if proof of accreditation is not supplied to the department

within eleven months of issuance of an accredited license.

(5) The owner or applicant of a medical test site must reapply for licensure within thirty days, if the acceptance of approval of the accreditation organization for the medical test site is denied or terminated.

(6) If at any time any of the changes listed in WAC 246-338-026 occur, the medical test site may require a different type of license than what the medical test site currently holds. If so, the owner must submit a reapplication form, within thirty days of the change, and pay applicable fees.

WAC 246-338-026 NOTIFICATION REQUIREMENTS

(1) The owner must notify the department in writing at least thirty days prior to the date of opening or closing the medical test site.

(2) The owner must notify the department in writing within thirty days of any changes in:
(a) Name of site;
(b) Director;
(c) Location of site;
(d) Tests, specialties and subspecialties; and
(e) Test methodologies.

(3) Proposed change of ownership. Transfer or reassignment of a license is prohibited without the department's approval, and must be initiated by the current owner sending a written notice to the department thirty days prior to transfer.
(a) The current owner of a medical test site must notify the department, in writing at least thirty days prior to the change and provide the following information:
(i) Name, address and federal tax ID number of the medical test site;
(ii) Full name, address, and location of the current owner and prospective new owner; and
(iii) The date of the proposed change of ownership.
(b) The prospective new owner must submit the following information at least thirty days prior to the change of ownership:
(i) New name and federal tax ID number of the medical test site;
(ii) Changes in technical personnel and supervisors;
(iii) Any changes in tests, specialties and subspecialties; and
(iv) Other information as requested by the department.

(4) The medical test site must authorize an approved accreditation organization to notify the department of the test site's compliance with the standards of the accreditation organization.

(5) The owner of an accredited license must notify the department in writing within thirty days of the medical test site having its accreditation denied or terminated by the accreditation organization or voluntarily dropping its accreditation status.

(6) The owner must notify the department in writing within thirty days of any convictions of fraud and abuse, false billing, or kickbacks under state or federal law.

WAC 246-338-028 ON-SITE INSPECTIONS

(1) The department may conduct an on-site review of a licensee or applicant at any time to determine compliance with chapter 70.42 RCW and this chapter as described in Table 020-1.

(2) The department may at any time examine records of the medical test site to determine compliance with chapter 70.42 RCW and this chapter.

(3) The department will:
(a) Provide written notice of deficiencies to the medical test site; and
(b) Allow the owner a reasonable period of time, not to exceed sixty days after department approval of the written plan of correction, to correct a deficiency unless the deficiency is an immediate threat to public health, safety, or welfare.

(4) The medical test site must:
(a) Present a written plan of correction to the department within fourteen days following the date of postmark of the notice of deficiencies;
(b) Comply with the written plan of correction within a specified time, not to exceed sixty days, after department approval of the written plan of correction which must detail how and when the medical test site will correct the deficiencies;
(c) Submit to inspections by CMS or CMS agents as a condition of licensure for the purpose of validation or in response to a complaint against the medical test site;

(d) Authorize the department to release all records and information requested by CMS to CMS or CMS agents;
(e) Cooperate with any on-site review conducted by the department; and
(f) Authorize the accreditation organization to submit, upon request of the department:
(i) On-site inspection results;
(ii) Reports of deficiencies;
(iii) Plans of corrections for deficiencies cited;
(iv) Any disciplinary or enforcement action taken by the accreditation organization against the medical test site and results of any disciplinary or enforcement action taken by the accreditation organization against the medical test site; and
(v) Any records or other information about the medical test site required for the department to determine whether or not standards are consistent with chapter 70.42 RCW and this chapter.

WAC 246-338-040 APPROVAL OF ACCREDITATION ORGANIZATIONS

(1) The department will recognize the accreditation organizations granted deemed status by CMS.

(2) The CMS-approved accreditation organizations are:
(a) American Association of Blood Banks (AABB);
(b) American Osteopathic Association (AOA);
(c) American Society of Histocompatability and Immunogenetics (ASHI);
(d) College of American Pathologists (CAP);
(e) COLA; and
(f) Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

(3) The accreditation organizations must:
(a) Allow the department to have jurisdiction to investigate complaints, do random on-site validation inspections, and take disciplinary action against a medical test site if indicated;
(b) Notify the department within fifteen days of any medical test site that:
(i) Has had its accreditation withdrawn, revoked, or limited;
(ii) Is sanctioned as a result of a routine inspection or complaint investigation; or
(iii) When adverse action has been taken for unsuccessful proficiency testing performance;
(c) Notify the department within five days of any deficiency that jeopardizes the public health, safety, or welfare; and
(d) Provide the department with a list of inspection schedules, as requested, for the purpose of conducting on-site validation inspections.

(4) The department will:
(a) Revoke deemed status from any organization which has deeming authority removed by CMS; and
(b) Notify the medical test site if approval of an accreditation organization is withdrawn by the department.

WAC 246-338-050 PROFICIENCY TESTING

(1) All licensed medical test sites, excluding those granted a certificate of waiver, must:
(a) Comply with federal proficiency testing requirements listed in 42 CFR Part 493-Laboratory Requirements, Subparts H and I;
(b) Submit to the department a copy of proficiency testing enrollment confirmation form(s) for the tests the medical test site will perform during the following calendar year, by December 31st of each year; and
(c) Authorize the proficiency testing program to release to the department all data required to determine the medical test site's compliance with this section.

(2) The department will:
(a) Recognize only those proficiency testing programs approved by HHS; and
(b) Furnish, upon request:
(i) A copy of 42 CFR Part 493 Subparts H and I;
(ii) A list of the proficiency testing programs approved by HHS; and
(iii) A list of tests that must be covered by proficiency testing.

(3) The department will evaluate proficiency testing results by using the following criteria:
(a) An evaluation of scores for the last three testing events of proficiency testing samples including:
(i) Tests;
(ii) Subspecialties; and
(iii) Specialties;
(b) Maintenance of a minimum acceptable score of eighty percent for all tests, subspecialties, and specialties except one hundred percent for:

(i) ABO grouping and Rh typing;
(ii) Compatibility testing; and
(iii) Antihuman immunodeficiency virus;
(c) Unsatisfactory performance occurs when:
(i) Unsatisfactory scores are obtained in any specialty or subspecialty in a testing event; or
(ii) An unsatisfactory score is obtained on a single test in a testing event.

(4) Unsatisfactory performance on two of any three successive testing events is considered unsuccessful participation, and will result in the following actions:
(a) The department will mail a letter to the director stating that the medical test site may choose to:
(i) Discontinue patient testing for the identified test, specialty or subspecialty; or
(ii) Follow a directed plan of correction; and
(b) The medical test site must notify the department, within fifteen days of receipt of the notice of the decision to:
(i) Discontinue testing patient specimens for the identified test, subspecialty or specialty; or
(ii) Agree to a directed plan of correction.

(5) Continued unsatisfactory performance for a test, specialty or subspecialty in either of the next two consecutive sets of proficiency testing samples, after completing a directed plan of correction, will result in the following action:
(a) The department will send, by certified mail, a notice to the owner and director of the medical test site to cease performing the identified test, subspecialty, or specialty; and
(b) The owner must notify the department in writing within fifteen days of the receipt of the notice of the decision to voluntarily stop performing tests on patient specimens for the identified test, subspecialty, or specialty.

(6) The owner may petition the department for reinstatement of approval to perform tests on patient specimens after demonstrating satisfactory performance on two successive testing events of proficiency testing samples for the identified test, subspecialty, or specialty.

(7) The department will notify the owner in writing, within fifteen days of receipt of petition, of the decision related to the request for reinstatement.

WAC 246-338-060 PERSONNEL

(1) Medical test site owners must:
(a) Have a director responsible for the overall technical supervision and management of the test site personnel including oversight of the performance of test procedures and reporting of test results;
(b) Have technical personnel, competent to perform tests and report test results; and
(c) Meet the standards for personnel qualifications and responsibilities in compliance with federal regulation, as listed in 42 CFR Part 493 Subpart M-Personnel for Nonwaived Testing.

(2) The department will furnish a copy of 42 CFR Part 493 Subpart M upon request.

(3) Medical test site directors must:
(a) Establish and approve policies for:
(i) Performing, recording, and reporting of tests;
(ii) Maintaining an ongoing quality assurance program;
(iii) Supervision of testing; and
(iv) Compliance with chapter 70.42 RCW and this chapter;
(b) Evaluate, verify, and document the following related to technical personnel:
(i) Education, experience, and training in test performance and reporting test results;
(ii) Sufficient numbers to cover the scope and complexity of the services provided;
(iii) Access to training appropriate for the type and complexity of the test site services offered; and
(iv) Maintenance of competency to perform test procedures and report test results;
(c) Be present, on call, or delegate the duties of the director to an on-site technical person during testing.

WAC 246-338-070 RECORDS

Medical test sites must maintain records as described in this section.

(1) REQUISITIONS must include the following information, in written or electronic form:
(a) Patient name, identification number, or other method of patient identification;
(b) Name and address or other suitable identifiers of the authorized person ordering the test;
(c) Date of specimen collection, and time, if appropriate;
(d) Source of specimen, if appropriate;

(e) Type of test ordered;
(f) Sex, and age or date of birth, of the patient; and
(g) For cytology and histopathology specimens:
(i) Pertinent clinical information; and
(ii) For Pap smears:
(A) Date of last menstrual period; and
(B) Indication whether the patient had a previous abnormal report, treatment, or biopsy.

(2) TEST RECORD SYSTEMS must:
(a) Consist of instrument printouts, worksheets, accession logs, corrective action logs, and other records that ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported; and
(b) Include:
(i) The patient's name or other method of specimen identification;
(ii) The date and time the specimen was received;
(iii) The reason for specimen rejection or limitation;
(iv) The date of specimen testing; and
(v) The identification of the personnel who performed the test.

(3) TEST REPORTS must:
(a) Be maintained in a manner permitting identification and reasonable accessibility;
(b) Be released only to authorized persons or designees;
(c) Include:
(i) Name and address of the medical test site, or where applicable, the name and address of each medical test site performing each test;
(ii) Patient's name and identification number, or a unique patient identifier and identification number;
(iii) Date reported;
(iv) Time reported, if appropriate;
(v) Specimen source, when appropriate, and any information regarding specimen rejection or limitation; and
(vi) Name of the test performed, test result, and units of measurement, if applicable.

(4) CYTOLOGY REPORTS must:
(a) Distinguish between unsatisfactory specimens and negative results;
(b) Provide narrative descriptions for any abnormal results, such as the 2001 Bethesda system of terminology as published in the Journal of the American Medical Association, 2002, Volume 287, pages 2114 -2119; and
(c) Include the signature or initials of the technical supervisor, or an electronic signature authorized by the technical supervisor, for nongynecological preparations and gynecological preparations interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial neoplasia lesions including human papillomavirus-associated changes) or malignant category.

(5) HISTOPATHOLOGY REPORTS must include the signature or initials of the technical supervisor or an electronic signature authorized by the technical supervisor on all reports.

(6) CYTOGENETICS REPORTS must:
(a) Use the International System for Human Cytogenetic Nomenclature on final reports;
(b) Include the number of cells counted and analyzed; and
(c) Include a summary and interpretation of the observations.

(7) If a specimen is referred to another laboratory for testing, the medical test site must:
(a) Report the essential elements of the referred test results without alterations that could affect the clinical interpretation of the results; and
(b) Retain or be able to produce an exact duplicate of each testing report from the referral laboratory.

(8) The medical test site must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

(9) If the medical test site ceases operation, it must make provisions to ensure that all records and, as applicable, slides, blocks and tissue are retained and available for the time frames specified in Table 070-1.

Table 070-1 Record/Slide/Tissue Retention Schedule

	Two Years	Five Years	Ten Years
(a) General Requirements for all Laboratory Specialties	▪ Test requisitions or equivalent; ▪ Test records, including instrument printouts if applicable; ▪ Test reports; ▪ Quality control records; ▪ Quality assurance records; ▪ Proficiency testing records; ▪ Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and ▪ Discontinued procedures for all specialty areas		
(b) Transfusion Services*		▪ Test requisitions or equivalent; ▪ Test records; ▪ Test reports; ▪ Quality control records; and ▪ Quality assurance records	
(c) Cytology		▪ All cytology slides, from date of examination of the slide	▪ All cytology reports
(d) Histopathology/ Oral Pathology	▪ Specimen blocks, from date of examination		▪ All histopathology and oral pathology reports; and ▪ Stained slides, from date of examination of the slide
(e) Histopathology/ Oral Pathology – Tissues	▪ Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic examination have been examined and diagnosed		
(f) Instrument/method Validation Studies	▪ For life of instrument/method plus two years		

*Must be retained for no less than five years in accordance with 21 CFR 606.160(d).

WAC 246-338-080 QUALITY ASSURANCE

Each medical test site performing moderate complexity (including PPMP) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program. The quality assurance program must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The medical test site's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable, and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the medical test site must revise policies and procedures based upon the results of those evaluations. The medical test site must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

(1) The medical test site must establish and implement a written quality assurance plan, including policies and procedures, designed to:
- (a) Monitor, evaluate, and review quality control data, proficiency testing results, and test results, including biannual verification of:
  - (i) Accuracy of test results for:
    - (A) Tests that are not covered by proficiency testing;
    - (B) Tests that are covered by proficiency testing but have unsatisfactory scores, are not scored by the proficiency testing program, or where scoring does not reflect actual test performance (e.g., the proficiency testing program does not obtain the agreement required for scoring; and
  - (ii) Relationship between test results when the medical test site performs the same test on different instruments or at different locations within the medical test site;
- (b) Identify and correct problems;
- (c) Establish and maintain accurate, reliable, and prompt reporting of test results;
- (d) Verify all tests performed and reported by the medical test site conform to specified performance criteria in quality control under WAC 246-338-090;
- (e) Establish and maintain the adequacy and competency of the technical personnel; and
- (f) Establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

(2) The quality assurance plan must include mechanisms or systems to:
- (a) Establish and apply criteria for specimen acceptance and rejection;
- (b) Notify the appropriate individuals as soon as possible when test results indicate potential life-threatening conditions;
- (c) Assess problems identified during quality assurance reviews and discuss them with the appropriate staff;
- (d) Evaluate all test reporting systems to verify accurate and reliable reporting, transmittal, storage, and retrieval of data;
- (e) Document all action taken to identify and correct problems or potential problems;
- (f) Issue corrected reports when indicated;
- (g) Provide appropriate instructions for specimen collection, handling, preservation, and transportation;
- (h) Ensure that specimens are properly labeled, including patient name or unique patient identifier and, when appropriate, specimen source;
- (i) Ensure confidentiality of patient information through all phases of the testing process; and
- (j) Provide clients updates of testing changes that would affect test results or the interpretation of test results.

(3) The medical test site must establish criteria for and maintain appropriate documentation of any remedial action taken in response to quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigations.

(4) When results of control or calibration materials fail to meet the established criteria for acceptability, the medical test site must have a system in place to determine if patient test results have been adversely affected. The system must include:
- (a) A review of all patient test results obtained in the unacceptable test run; and
- (b) A review of all patient test results since the last acceptable test run.

(5) The medical test site must have a system in place to assure:
(a) All complaints and problems reported to the medical test site are documented and investigated when appropriate; and
(b) Corrective actions are instituted as necessary.

(6) The owner must:
(a) Maintain adequate space, facilities, and essential utilities for the performance and reporting of tests;
(b) Ensure that molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and production detection, and as applicable, reagent preparation;
(c) Establish, make accessible, and observe safety precautions to ensure protection from physical, chemical, biochemical, and electrical hazards and biohazards; and
(d) Establish and implement policies and procedures for infectious and hazardous medical wastes consistent with local, state, and federal authorities.

(7) Information that must be available to authorized persons ordering or utilizing the test results includes:
(a) A list of test methods, including performance specifications;
(b) Reference ranges; and
(c) Test method limitations.

(8) If the medical test site refers specimens to another site for testing, the site to which specimens are referred must have a valid medical test site license or meet equivalent requirements as determined by CMS.

WAC 246-338-090 QUALITY CONTROL

The medical test site must use quality control procedures, providing and assuring accurate and reliable test results and reports, meeting the requirements of this chapter.

(1) The medical test site must have written procedures and policies available in the work area for:
(a) Analytical methods used by the technical personnel including:
(i) Principle;
(ii) Specimen collection and processing procedures;
(iii) Equipment/reagent/supplies required;
(iv) Preparation of solutions, reagents, and stains;
(v) Test methodology;
(vi) Quality control procedures;
(vii) Procedures for reporting results (normal, abnormal, and critical values);
(viii) Reference range;
(ix) Troubleshooting guidelines - limitations of methodology;
(x) Calibration procedures; and
(xi) Pertinent literature references; and
(b) Alternative or backup methods for performing tests including the use of a reference facility if applicable.

(2) The medical test site must establish written criteria for and maintain appropriate documentation of:
(a) Temperature-controlled spaces and equipment;
(b) Preventive maintenance activities;
(c) Equipment function checks;
(d) Procedure calibrations; and
(e) Method/instrument validation procedures.

(3) The medical test site must maintain documentation of:
(a) Expiration date, lot numbers, and other pertinent information for:
(i) Reagents;
(ii) Solutions;
(iii) Culture media;
(iv) Controls;
(v) Calibrators;
(vi) Standards;
(vii) Reference materials; and
(viii) Other testing materials; and
(b) Testing of quality control samples.

(4) For **quantitative tests,** the medical test site must perform quality control as follows:
(a) Include two reference materials of different concentrations each day of testing unknown samples, if these reference materials are available; or
(b) Follow an equivalent quality testing procedure that meets federal CLIA regulations.

(5) For **qualitative tests,** the medical test site must perform quality control as follows:
(a) Use positive and negative reference material each day of testing unknown samples; or
(b) Follow an equivalent quality testing procedure that meets federal CLIA regulations.

(6) The medical test site must:
- (a) Use materials within their documented expiration date;
- (b) Not interchange components of kits with different lot numbers, unless specified by the manufacturer;
- (c) Determine the statistical limits for each lot number of unassayed reference materials through repeated testing;
- (d) Use the manufacturer's reference material limits for assayed material, provided they are:
  - (i) Verified by the medical test site; and
  - (ii) Appropriate for the methods and instrument used by the medical test site;
- (e) Make reference material limits readily available;
- (f) Report patient results only when reference materials are within acceptable limits; and
- (g) Rotate control material testing among all persons who perform the test;
- (h) Use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system, if using calibration material as a control material; and
- (i) Comply with general quality control requirements as described in Table 090-1, unless otherwise specified in subsection (9)(a) through (l) of this section.

(7) The medical test site must perform, when applicable:
- (a) Calibration and calibration verification for **moderate and high complexity testing** as described in Table 090-2;
- (b) Validation for **moderate complexity testing** by verifying the following performance characteristics when the medical test site introduces a new procedure classified as moderate complexity:
  - (i) Accuracy;
  - (ii) Precision;
  - (iii) Reportable range of patient test results; and
  - (iv) If using the reference range provided by the manufacturer, that it is appropriate for the patient population;
- (c) Validation for **high complexity testing:**
  - (i) When the medical test site introduces a new procedure classified as high complexity;
  - (ii) For each method that is developed in-house, is a modification of the manufacturer's test procedure, or is an instrument, kit or test system that has not been cleared by FDA; and
  - (iii) By verifying the following performance characteristics:
    - (A) Accuracy;
    - (B) Precision;
    - (C) Analytical sensitivity;
    - (D) Analytical specificity to include interfering substances;
    - (E) Reference ranges (normal values);
    - (F) Reportable range of patient test results; and
    - (G) Any other performance characteristic required for test performance.

(8) When patient values are above the maximum or below the minimum calibration point or the reportable range, the medical test site must:
- (a) Report the patient results as greater than the upper limit or less than the lower limit or an equivalent designation;
- (b) Use an appropriate procedure to rerun the sample allowing results to fall within the established linear range.

Table 090-1 General Quality Control Requirements

	Control Material	Frequency
(a) Each batch or shipment of reagents, discs, antisera, and identification systems	• Appropriate control materials for positive and negative reactivity	• When prepared or opened, unless otherwise specified
(b) Each batch or shipment of stains	• Appropriate control materials for positive and negative reactivity	• When prepared or opened; and • Each day of use, unless otherwise specified
(c) Fluorescent and immunohistochemical stains	• Appropriate control materials for positive and negative reactivity	• Each time of use, unless otherwise specified
(d) Quality control for each specialty and subspecialty	• Appropriate control materials; or • Equivalent mechanism to assure the quality, accuracy, and precision of the test if reference materials are not available	• At least as frequently as specified in this section; • More frequently if recommended by the manufacturer of the instrument or test procedure; or • More frequently if specified by the medical test site
(e) Direct antigen detection systems without procedural controls	• Positive and negative controls that evaluate both the extraction and reaction phase	• Each batch, shipment, and new lot number; and • Each day of use

Table 090-2 Calibration and Calibration Verification – Moderate and High Complexity Testing

	Calibration Material	Frequency
CALIBRATION	• Calibration materials appropriate for methodology	• Initial on-site installation/implementation of instrument/method; • At the frequency recommended by the manufacturer; and • Whenever calibration verification fails to meet the medical test site's acceptable limits for calibration verification.
CALIBRATION VERIFICATION	• Use assayed material, if available, at the lower, mid-point, and upper limits of procedure's reportable range; or • Demonstrate alternate method of assuring accuracy at the lower, mid-point, and upper limits of procedure's reportable range	• At least every six months; • When there is a complete change of reagents (*i.e.*, new lot number or different manufacturer) is introduced; • When major preventive maintenance is performed or there is a replacement of critical parts of equipment; or • When controls are outside of the medical test site's acceptable limits or exhibit trends.

(9) The medical test site must perform quality control procedures as described for each specialty and subspecialty in (a) through (l) of this subsection.

(a) Chemistry: **Perform quality control procedures for chemistry as described in Table 090-3** or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-3 Quality Control Procedures - Chemistry

Subspecialty/Test	Qualitative		Quantitative	
	Control Material	Frequency	Control Material	Frequency
Routine Chemistry	• Positive and negative reference material	• Each day of use	• Two levels of reference material in different concentrations	• Each day of use
Toxicology				
• GC/MS for drug screening	• Analyte-specific control	• With each run of patient specimens	• Analyte-specific control	• With each analytical run
• Urine drug screen	• Positive control containing at least one drug representative of each drug class to be reported; must go through each phase of use including extraction	• With each run of patient specimens		
Urinalysis				
• Non-waived instrument			• Two levels of control material	• Each day of use
• Refractometer for specific gravity			• Calibrate to zero with distilled water • One level of control material	• Each day of use
Blood Gas Analysis			• Calibration	• Follow manufacturer's specifications and frequency
			• One level of control material	• Each 8 hours of testing, using both low and high values on each day of testing
			• One-point calibration or one control material	• Each time patient specimen is tested, unless automated instrument internally verifies calibration every thirty minutes
Electrophoresis	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell

(b) Hematology:

(i) Run patient and quality control samples in duplicate for manual cell counts;

(ii) If reference material is unavailable, document the mechanism used to assure the quality, accuracy, and precision of the test; and

(iii) Perform quality control procedures for hematology as described in Table 090-4 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-4 Quality Control Procedures - Hematology

	Control Material	Frequency
Automated	• Two levels of reference material in different concentrations	• Each day that patient samples are tested
Manual Blood Counts	• One level of reference material	• Every 8 hours that patient samples are tested
Qualitative Tests	• Positive and negative reference material	• Each day of testing

(c) Coagulation:

(i) Run patient and quality control samples in duplicate for manual coagulation test (tilt tube);

(ii) If reference material is unavailable, document the mechanism used to assure the quality, accuracy and precision of the test; and

(iii) Perform quality control procedures for coagulation as described in Table 090-5 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-5 Quality Control Procedures - Coagulation

	Control Material	Frequency
Automated	• Two levels of reference material in different concentrations	• Every 8 hours that patient samples are tested; and • Each time reagents are changed
Manual Tilt Tube Method	• Two levels of reference material in different concentrations	• Every 8 hours that patient samples are tested; and • Each time reagents are changed

(d) General Immunology:

(i) Employ reference materials for all test components to ensure reactivity;
(ii) Report test results only when the predetermined reactivity pattern of the reference material is observed; and
(iii) Perform quality control procedures for general immunology as described in Table 090-6 or follow an equivalent quality testing procedure that meets federal CLIA regulations.

Table 090-6 Quality Control Procedures - General Immunology

	Control Material	Frequency
Serologic tests on unknown specimens	• Positive and negative reference material	• Each day of testing
Kits with procedural (internal) controls	• Positive and negative reference material (external controls)	• When kit is opened; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations
	• Procedural (internal) controls	• Each time patient sample is tested

(e) Syphilis Serology:
(i) Use equipment, glassware, reagents, controls, and techniques that conform to manufacturer's specifications;
(ii) Employ reference materials for all test components to ensure reactivity; and
(iii) Perform serologic tests on unknown specimens each day of testing with a positive serum reference material with known titer or graded reactivity and a negative reference material.

(f) Microbiology:
(i) Have available and use:
(A) Appropriate stock organisms for quality control purposes; and
(B) A collection of slides, photographs, gross specimens, or text books for reference sources to aid in identification of microorganisms;
(ii) Document all steps (reactions) used in the identification of microorganisms on patient specimens;
(iii) For antimicrobial susceptibility testing:
(A) Record zone sizes or minimum inhibitory concentration for reference organisms; and
(B) Zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results; and
(C) Perform quality control on antimicrobial susceptibility testing media as described in Table 090-8;
(iv) For noncommercial media, check each batch or shipment for sterility, ability to support growth and, if appropriate, selectivity, inhibition, or biochemical response;
(v) For commercial media:
(A) Verify that the product insert specifies that the quality control checks meet the requirements for media quality control as outlined by the NCCLS, Quality Assurance for Commercially Prepared Microbiological Culture Media-Second Edition; Approved Standard (1996);
(B) Keep records of the manufacturer's quality control results;
(C) Document visual inspection of the media for proper filling of the plate, temperature or shipment damage, and contamination before use; and
(D) Follow the manufacturer's specifications for using the media; and
(vi) For microbiology subspecialties:

(A) Bacteriology: Perform quality control procedures for bacteriology as described in Tables 090-7 and 090-8.

Table 090-7 Quality Control Procedures - Bacteriology

	Control Material	Frequency
Reagents, disks, and identification systems Catalase, coagulase, oxidase, and Beta-lactamase Cefinase™ reagents Bacitracin, optochin, ONPG, X and V disks or strips	• Positive and negative reference organisms, unless otherwise specified	• Each batch, shipment and new lot number unless otherwise specified
Stains, unless otherwise specified; DNA probes; and all beta-lactamase methods other than Cefinase™	• Positive and negative reference organisms	• Each batch, shipment and new lot number; and • Each day of use
Fluorescent stains	• Positive and negative reference organisms	• Each batch, shipment and new lot number; and • Each time of use
Gram stains	• Positive and negative reference organisms	• Each batch, shipment and new lot number; and • Each week of use
Direct antigen detection systems without procedural controls	• Positive and negative controls that evaluate both the extraction and reaction phase	• Each batch, shipment and new lot number; and • Each day of use
Test kits with procedural (internal) controls	• Positive and negative reference material (external) controls	• Each batch, shipment and new lot number; and • Each day of testing, or follow an equivalent quality testing procedure that meets federal CLIA regulations
	• Procedural (internal) controls	• Each time patient sample is tested
Antisera	• Positive and negative reference material	• Each batch, shipment and new lot number; and • Every six months

Table 090-8 Quality Control Procedures - Bacteriology – Media for Antimicrobial Susceptibility Testing

	Control Material	Frequency
Check each new batch of media and each new lot of antimicrobial disks or other testing systems (MIC)	• Approved reference organisms (ATCC organisms)	• Before initial use and each day of testing; or • May be done weekly if the medical test site can meet the quality control requirements for antimicrobial disk susceptibility testing as outlined by NCCLS Performance Standards for Antimicrobial Disk Susceptibility Tests-Eighth Edition; Approved Standard (2003)

(B) Mycobacteriology: Perform quality control procedures for mycobacteriology as described in Table 090-9.

Table 090-9 Quality Control Procedures - Mycobacteriology

	Control Material	Frequency
All reagents or test procedures used for mycobacteria identification unless otherwise specified	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each day of use
Acid-fast stains	• Acid-fast organism that produces a positive reaction and an organism that produces a negative reaction	• Each day of use
Fluorochrome acid-fast stains	• Acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction	• Each time of use
Susceptibility tests performed on *Mycobacterium tuberculosis* isolates	• Appropriate control organism(s)	• Each batch of media, and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use • Each week of use

(C) Mycology: Perform quality control procedures for mycology as described in Table 090-10.

Table 090-10 Quality Control Procedures - Mycology

	Control Material	Frequency
Susceptibility tests: each drug NOTE: Establish control limits and criteria for acceptable control results prior to reporting patient results	• One control strain that is susceptible to the drug	• Each day of use
Lactophenol cotton blue stain	• Appropriate control organism(s)	• Each batch or shipment and each lot number
Acid-fast stains	• Organisms that produce positive and negative reactions	• Each day of use
Reagents for biochemical and other identification test procedures	• Appropriate control organism(s)	• Each batch or shipment and each lot number
Commercial identification systems utilizing 2 or more substrates	• Organisms that verify positive and negative reactivity of each media type	• Each batch or shipment and each lot number

(D) Parasitology:

(I) Have available and use:

- Reference collection of slides or photographs and, if available, gross specimens for parasite identification; and
- Calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(II) Check permanent stains each month of use with reference materials.

(E) Virology:

(I) Have available:

- Host systems for isolation of viruses; and
- Test methods for identification of viruses that cover the entire range of viruses that are etiologically related to the clinical diseases for which services are offered; and

(II) Simultaneously culture uninoculated cells or cell substrate as a negative control when performing virus identification.

(g) Histopathology: Include a control slide of known reactivity with each slide or group of slides for differential or special stains and document reactions.

(h) Cytology:

(i) Processing Specimens:

(A) Stain all gynecological smears using a Papanicolaou or a modified Papanicolaou staining method;

(B) Have methods to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process; and

(C) Stain nongynecological specimens that have a high potential for cross-contamination separately from other nongynecological specimens, and filter or change the stains following staining.

(ii) Performing Specimen Examinations:

(A) All cytology preparations must be evaluated on the premises of the medical test site;

(B) Technical personnel must examine, unless federal law and regulation specify otherwise, no more than one hundred cytological slides (one patient specimen per slide; gynecologic, nongynecologic, or both) in a twenty-four-hour period and in no less than an eight-hour work period;

(C) Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecological cases and previously examined nongynecologic cytology preparations and tissue pathology slides examined by a technical supervisor are not included in the one hundred slide limit;

(D) Each nongynecologic slide preparation made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

(E) Records of the total number of slides examined by each individual at all sites during each twenty-four-hour period must be maintained.

(iii) Establish and implement a quality assurance program that ensures:

(A) There is criteria for submission of material;

(B) All providers submitting specimens are informed of these criteria;

(C) All samples submitted are assessed for adequacy;

(D) Records of initial examinations and rescreening results are available and documented;

(E) Rescreening of benign gynecological slides is:

(I) Performed by an individual who meets the personnel requirements for technical or general supervisor in cytology as defined under 42 CFR Part 493 Subpart M;

(II) Completed before reporting patient results on those selected cases;

(III) Performed and documented on:

- No less than ten percent of the benign gynecological slides; and
- Includes cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer,

based on available patient information;

(F) The technical supervisor:
(I) Confirms all gynecological smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial neoplasia lesions including human papillomavirus-associated changes) or malignant category;
(II) Reviews all nongynecological cytological preparations; and
(III) Establishes, documents and reassesses, at least every six months, the workload limits for each cytotechnologist;
(G) All cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms are correlated with prior cytology reports and with histopathology reports if available, and the causes of any discrepancies are determined;
(H) Review of all normal or negative gynecological specimens received within the previous five years, if available in the laboratory system, or records of previous reviews, for each patient with a current high grade intraepithelial lesion or moderate dysplasia or CIN-2 or above;
(I) Notification of the patient's physician if significant discrepancies are found that would affect patient care and issuance of an amended report;
(J) An annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis, number of cases where cytology and histology are discrepant, number of cases where histology results were unavailable for comparison, and number of cases where rescreen of negative slides resulted in reclassification as abnormal; and
(K) Evaluation and documentation of the performance of each individual examining slides against the medical test site's overall statistical values, with documentation of any discrepancies, including reasons for the deviation and corrective action, if appropriate.

(i) Immunohematology/Transfusion Services:
(i) Perform ABO grouping, Rh (D) typing, antibody detection and identification, and compatibility testing as described by the Food and Drug Administration (FDA) under 21 CFR Parts 606 and 640.
(A) Perform ABO grouping:
(I) By concurrently testing unknown red cells with FDA approved anti-A and anti-B grouping sera;
(II) Confirm ABO grouping of unknown serum with known A1 and B red cells;
(B) Perform Rh (D) typing by testing unknown red cells with anti-D (anti-Rh) blood grouping serum; and
(C) Perform quality control procedures for immunohematology as described in Table 090-11.
(ii) Blood and Blood Products:
(A) Collecting, processing, and distributing:
(I) Must comply with FDA requirements listed under 21 CFR Parts 606, 610.40, 610.53, and 640; and
(II) Must establish, document, and follow policies to ensure positive identification of a blood or blood product recipient.
(B) Labeling and dating must comply with FDA requirements listed under 21 CFR 606 Subpart G, and 610.53.
(C) Storing:
(I) There must be an adequate temperature alarm system that is regularly inspected.
(II) The system must have an audible alarm system that monitors proper blood and blood product storage temperature over a twenty-four hour period.

(III) High and low temperature checks of the alarm system must be documented.

(D) Collection of heterologous or autologous blood products on-site:

(I) Must register with the FDA; and

(II) Have a current copy of the form FDA 2830 "Blood Establishment Registration and Product Listing".

(iii) Must have an agreement approved by the director for procurement, transfer, and availability to receive products from outside entities.

(iv) Promptly investigate transfusion reactions according to established procedures, and take any necessary remedial action.

Table 090-11 Quality Control Procedures - Immunohematology

Reagent	Control Material	Frequency
ABO antisera	• Positive control	• Each day of use
Rh antisera	• Positive and negative controls • Patient control to detect false positive Rh test results	• Each day of use • When required by the manufacturer
Other antisera	• Positive and negative controls	• Each day of use
ABO reagent red cells	• Positive control	• Each day of use
Antibody screening cells	• Positive control using at least one known antibody	• Each day of use

(j) Histocompatibility:

(i) Use applicable quality control standards for immunohematology, transfusion services, and diagnostic immunology as described in this chapter; and

(ii) Meet the standards for histocompatibility as listed in 42 CFR Part 493.1278, Standard: Histocompatibility, available from the department upon request.

(k) Cytogenetics:

(i) Document:

(A) Number of metaphase chromosome spreads and cells counted and karyotyped;

(B) Number of chromosomes counted for each metaphase spread;

(C) Media used;

(D) Reactions observed;

(E) Quality of banding; and

(F) Sufficient resolution appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided;

(ii) Assure an adequate number of karyotypes are prepared for each patient according to the indication given for performing cytogenetics study;

(iii) Use an adequate patient identification system for:

(A) Patient specimens;

(B) Photographs, photographic negatives, or computer stored images of metaphase spreads and karyotypes;

(C) Slides; and

(D) Records; and

(iv) Perform full chromosome analysis for determination of sex.

(l) Radiobioassay and Radioimmunoassay:

(i) Check the counting equipment for stability each day of use with radioactive standards or reference sources; and

(ii) Meet Washington State radiation standards described under chapter 70.98 RCW and chapters 246-220, 246-221, 246-222, 246-232, 246-233, 246-235, 246-239, 246-247, 246-249, and 246-254 WAC.

WAC 246-338-100 DISCIPLINARY ACTION

(1) Pursuant to chapter 34.05 RCW, the department may deny a license to any applicant, or condition, suspend, or revoke the license of any licensee, or in addition to or in lieu thereof, assess monetary penalties of up to ten thousand dollars per violation, if the applicant or licensee:

(a) Fails or refuses to comply with the requirements of chapter 70.42 RCW or the rules adopted under chapter 70.42 RCW;

(b) Knowingly, or with reason to know, makes a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(c) Refuses to allow representatives of the department to examine any book, record, or file required under this chapter;

(d) Willfully prevents, interferes with, or attempts to impede in any way, the work of a representative of the department; or

(e) Misrepresents or is fraudulent in any aspect of the owner's or applicant's business.

(2) The department may impose the sanctions enumerated in subsection (1) of this section individually or in any combination.

(3) The sanction shall be as specified for the following described conduct. If more than one sanction is listed, the department may impose the sanction individually or in any combination:

(a) If the applicant was the holder of a license under chapter 70.42 RCW which was revoked for cause and never reissued by the department, then the license application may be denied;

(b) If the licensee willfully prevents or interferes with preservation of evidence of a known violation of chapter 70.42 RCW or the rules adopted under this chapter, a monetary penalty not exceeding ten thousand dollars per violation may be assessed or the license may be:

(i) Conditioned in a manner limiting or canceling the authority to conduct tests or groups of tests;

(ii) Suspended;

(iii) Revoked;

(c) If the licensee used false or fraudulent advertising, a monetary penalty not exceeding ten thousand dollars per violation may be assessed or the license may be suspended or revoked;

(d) If the licensee failed to pay any civil monetary penalty assessed by the department under chapter 70.42 RCW within twenty-eight days after the assessment becomes final, the license may be suspended or revoked;

(e) If the licensee intentionally referred its proficiency testing samples to another medical test site or laboratory for analysis, the license will be revoked for a period of at least one year and a monetary penalty not exceeding ten thousand dollars per violation may be assessed.

(4) The department may summarily suspend or revoke a license when the department finds continued licensure of a test site immediately jeopardizes the public health, safety, or welfare.

(5) The department will give written notice of any disciplinary action taken by the department to the owner or applicant for licensure, including notice of the opportunity for a hearing.

WAC 246-338-110 ADJUDICATIVE PROCEEDINGS

(1) A licensee or applicant who contests a disciplinary action shall, within twenty-eight days of service of the notice of disciplinary action, file a request for adjudicative proceeding with the Department of Health, Adjudicative Clerk , P. O. Box 47879, Olympia, WA 98504-7879.

(2) The adjudicative proceeding is governed by chapter 34.05 RCW, the Administrative Procedure Act, chapter 70.42 RCW, Medical Test Sites, this chapter, and chapter 246-10 WAC.

(3) Any licensee or applicant aggrieved upon issuance of the decision after the adjudicative proceeding may, within sixty days of service of the adjudicative proceeding decision, petition the superior court for review of the decision under chapter 34.05 RCW.

WAC 246-338-990 FEES

(1) The department will assess and collect biennial fees for medical test sites as follows:

(a) Charge fees, based on the requirements authorized under RCW 70.42.090 and this section;

(b) Assess additional fees when changes listed in WAC 246-338-026 occur that require a different type of license than what the medical test site currently holds; and

(c) Determine fees according to criteria described in Table 990-1.

(2) The following programs are excluded from fee charges when performing only waived

hematocrit or hemoglobin testing for nutritional evaluation and food distribution purposes:

(a) Women, infant and children programs (WIC); and

(b) Washington state migrant council.

Table 990-1 License Categories and Fees

Category of License	Number of Tests/Year	Biennial Fee
Certificate of Waiver	N/A	$ 150
PPMP	N/A	$ 200
Low Volume	1-2,000 tests	$ 450
Category A	2,001-10,000 tests, 1-3 specialties	$ 1,364
Category B	2,001-10,000 tests, 4 or more specialties	$ 1,769
Category C	10,001-25,000 tests, 1-3 specialties	$ 2,454
Category D	10,001-25,000 tests, 4 or more specialties	$ 2,818
Category E	25,001-50,000 tests	$ 3,382
Category F	50,001-75,000 tests	$ 4,187
Category G	75,001-100,000 tests	$ 4,991
Category H	100,001-500,000 tests	$ 5,835
Category I	500,001-1,000,000 tests	$10,369
Category J	> 1,000,000 tests	$12,443
Accredited		
Low Volume	1-2,000 tests	$ 165
Category A	2,001-10,000 tests, 1-3 specialties	$ 211
Category B	2,001-10,000 tests, 4 or more specialties	$ 231
Category C	10,001-25,000 tests, 1-3 specialties	$ 531
Category D	10,001-25,000 tests, 4 or more specialties	$ 559
Category E	25,001-50,000 tests	$ 787
Category F	50,001-75,000 tests	$ 1,254
Category G	75,001-100,000 tests	$ 1,722
Category H	100,001-500,000 tests	$ 2,227
Category I	500,001-1,000,000 tests	$ 6,428
Category J	> 1,000,000 tests	$ 8,168
Follow up survey for deficiencies		Direct staff time
Complaint investigation		Direct staff time